GUIDELINE FOR CONVENED BOARD REVIEW OF RESEARCH

The Office for Human Subject Protection (OHSP) Policy 501 describes the levels of RSRB review for proposed research activities, including the type of research that will undergo convened board review procedures according to the regulations of HHS 45 CFR 46.110 and FDA 21 CFR 56.11. This guideline describes the regulatory categories, institutional standards, and procedures for the convened board review process by the RSRB.

1. Investigator Submission Requirements

   a. When submitting applications for initial, continuing or amendment review, Investigators must include all applicable materials for submission listed in OHSP Policy 502 Types of RSRB Submissions.
      - The applicable Protocol Template and Consent Form Templates may be utilized to ensure regulatory and institutional standards are met.

   b. Upon receipt of an application by the RSRB Specialist, a pre-review of the submission will be completed (e.g., to verify whether the submission materials are completed, required education is completed, etc.). The Specialist may request more information from the Investigator or from the Board Chair during this pre-review process for clarification or completeness of the application. Once the application is considered complete for purposes of board review, the study will be processed for the convened board review. If appropriate, the Specialist may re-assign the application for consideration of expedited review (see OHSP Guideline for Expedited Review of Research).

2. Board Reviewer Assignments

   a. The RSRB Specialist (or designee) assigns the protocol to a board member with the appropriate expertise (which may include the Board Chair). The following will be considered when making this assignment and the Specialist may consult with the RSRB Chair in making the decision:
      - Reviewer’s workload (i.e., other study assignments).
      - Potential conflicts of interest (OHSP Policy 902 Investigator Conflict of Interest).
      - Need for special representation (e.g., vulnerable populations such as children or prisoners).

   b. The designated RSRB reviewer is notified by the RSRB on-line submission system (ROSS) that a study has been assigned.

   c. If it is determined at any point during the review process that supplemental review by a consultant is necessary, the process outlined in OHSP Policy 402 RSRB Meetings for “Selection of Consultants” will be followed.
3. Convened Board Review Procedures

a. Initial and Continuing Review
   i. The assigned RSRB primary reviewer and RSRB members will conduct an in-depth review of submitted materials according to OHSP Policy 402 RSRB Meetings. In addition, for continuing review, all previous reviews and approved materials are available to the reviewer and board members.

   ii. During the continuing review of research, the convened board will assess, as applicable, subject enrollment, study personnel, reportable events, consent and documentation of consent, research results, previously approved amendments, data and safety monitoring reports, publications and any other items relevant to the level of research risk and ongoing conduct of the research to determine the following:
      - The current or proposed consent document is accurate and complete;
      - Whether significant new findings that might relate to the subject’s willingness to continue participation in the research need to be provided to the subject;
      - Whether verification from sources other than the Investigator is needed to ensure that no material changes have occurred since prior RSRB review.
      - Whether all elements of the criteria for approval, per OHSP Policy 404 Criteria for RSRB Approval of Research, are still applicable as initially determined by the convened board.

b. Changes (Amendments) to Previously Approved Research
   i. Examples of amendments requiring review by the convened board include:
      - Expansion of the eligibility criteria to a study involving greater than minimal risk;
      - Increasing the total enrollment goal to a study involving greater than minimal risk;
      - Alterations in the dosage or route of administration;
      - Discovery of additional toxicities prompting revision to the consent form;
      - Changes which, in the opinion of the RSRB Chair or designee, should be referred to the convened board.

   ii. The RSRB reviewer and RSRB members will conduct an in-depth review of the Amendment Form and revised materials according to OHSP Policy 402 RSRB Meetings. All previous reviews and approved materials are available to all RSRB members for review.

   iii. The convened board will review and discuss the submitted information and determine the following:
      - Whether the amendment affects one or more criterion for approval, as described in OHSP Policy 404 Criteria for RSRB Approval of Research;
      - Whether the amendment increases the risk to subjects who participate;
      - Whether significant new findings that might relate to the subject’s willingness to continue participation in the research need to be provided to
the subject (i.e., re-consent of subjects previously enrolled and continuing research activities or interventions) and the method for such notification (e.g., consent revision, consent addendum, or new consent form).

4. Convened Board Review Determinations and Notifications

a. Once a review determination is made, the board’s decision will be recorded electronically in ROSS and in the meeting minutes. The possible RSRB voting motions that can be taken include approval as submitted, approval with stipulations, table, disapprove, or suspension (or termination for an active study) as outlined in OHSP Policy 402 RSRB Meetings.

- When stipulations are requested, the Investigator may respond to the requested changes or provide justification for not doing so. The Board Chair, or experienced member, in conjunction with the RSRB Specialist, makes a determination whether or not the Investigator addressed all stipulations required by the board. If all stipulations are addressed, the study is submitted for approval. If not all stipulations are addressed, or the Investigator’s response includes considerable revisions beyond the scope of the convened board’s requested stipulations, the application and Investigator’s response will be reviewed according to OHSP Policy 402 RSRB Meetings.

- At the time of initial review, the RSRB reviewer may approve some components of the research study and allow an Investigator to initiate research activities only related to those approved components, and defer action on other components (see OHRP Guidance on IRB Approval of Research with Conditions).

b. Once the initial, continuing or amendment review is approved as described in OHSP Policy 404 Criteria for RSRB Approval of Research, the RSRB Chair (or designee) completes the applicable RSRB Chair approval checklist (i.e., new protocol, continuing review, or amendment checklist) to document the research was approved by the convened board, any required regulatory findings, and the approval period for initial and continuing reviews. Additional comments regarding the review determination may be included in the checklist, as applicable, including an explanation for any protocol requiring review more often than annually.

c. Determination of approval periods will be made as follows, with the expiration date being the last date the research activities may be conducted.

i. For initial review, the approval period start and end dates are determined based on the date of the board meeting and date of Chair signature as indicated below:

- Initial Review Start Date = Date of the convened board meeting if approved without stipulations; otherwise, the date the Chair signs the approval letter confirming the conditions of approval have been satisfied.
- Initial Review Expiration Date = One year from convened board meeting date, minus one day (e.g., meeting date 04/10/2013 means expiration date is 04/09/2014).
For **continuing review**, the approval period should be 364 days, i.e., one year minus one day from start date, as follows:

- **Re-approval Start Date** = Initial review expiration date of 04/09/2014 means the start date of re-approval period is 04/10/2014.
  - **Note:** Day the Chair signs re-approval letter and re-approval start date may differ.

- **Re-approval Expiration Date** = The year changes and the month and day remains the same as the initial review expiration (e.g., initial review expiration is 04/09/2014; therefore, re-approval expiration date is 04/09/2015).

iii. Exceptions for determining approval periods:

**Exception 1 – Studies That Expired:**
The re-approval start date is the date the Chair signs the letter (e.g., board reviews study with lapsed expiration date of 10/08/13, the Chair signs the letter on 10/22/13, so the re-approval period is 10/22/13 through 10/08/14). **In this case, the wording on the re-approval letter for lapsed studies should also include the following:** No RSRB approval from 10/09/13 through 10/21/13. The lapse in study approval will start one day after the study expired and will end one day before the Chair signs the letter.

**Exception 2 – Studies With Approval Period Less Than 1 Year:**
If the Board approves a study for less than 1 year, e.g., 6 months, then the expiration date (month/day) will not remain the same (e.g., an initial approval start date of 10/05/13 with approval period for 6 months only means expiration date is 04/04/14). For re-approval, in this case, the start date will be 04/05/14 and the expiration date will be 10/04/14.

d. Investigators are notified of convened board review actions according to OHSP **Policy 403 Notification of RSRB Determinations**.

e. The Institutional Official (IO), or as delegated to the OHSP Director, is notified of all research that is approved by convened board review procedures through review of the meeting minutes on a regular basis, or that may be accessed directly from ROSS or the network shared drive.
  - If research requires further action or review by the UR as determined by the IO (or designee), the requirements will be communicated to the Director of the RSRB and RSRB Chair.